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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,491	04/22/2004	Ing-Ming Chiu	28489/04001	7628

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EXAMINER
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LIETO, LOUIS D

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/829,491

Applicant(s)

CHIU, ING-MING

Examiner

Louis D. Lieto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,15-19 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,15-19 and 40-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's response filed on 7/14/2005 is acknowledged. Claims 1-11, 15-33, and 37-40 are pending in the instant application. Applicant amended claims 1, 5, 6, 15-19, and 40, cancelled claims 2-4, 7-14, 20-33 and 37-39, and added new claims 41 and 42.

Claims 1, 5, 6, 15-19, and 40-42 are currently under consideration.

The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

The rejection of claims 1-5, 9-11, 16-24, 28-33 and 37-40 under 35 U.S.C. 103(a) as being unpatentable over Alam et al. (The Journal of Biological Chemistry. Vol. 271:30263-30271, 1996) or Ray et al. (The Journal of Biological Chemistry. Vol. 272: 7546-7555, 1997) in view of Takahashi et al (Exp. Anim. 48:255-261, 1999) and Perraud et al. (Oncogene Vol. 7:993-997, 1992) is withdrawn in view of applicant's amendments, arguments and cancellation of claims.

### ***Sequence Compliance***

The objection over this application for failing to comply with the requirements of 37 CFR 1.821 through 1.825 is withdrawn because of applicant's submission of SEQ ID No. as a computer readable form copy.

### ***Claim Objections***

Claims 1, 5 and 16 objected to because of the following informalities: The claims contain awkward and imprecise language.

The Office suggests the following amendments to the claims:

1. A transgenic mouse whose genome comprises a transgene comprising a mouse FGF1B promoter or a human FGF1B promoter, operably linked to a DNA fragment comprising a sequence encoding the SV40 large T antigen, wherein said mouse exhibits brain tumor cells that do not express glial fibrillary acidic protein, S-100, synaptophysin and neuron-specific enolase.
5. The transgenic mouse of claim 1, wherein the promoter comprises nucleotide -540 through nucleotide +31 of the human FGF1B promoter depicted in SEQ ID NO:2 as nucleotide 10 to nucleotide 580.
16. A brain tumor cell line derived from the tumor cells of the transgenic mouse of claim 1, wherein said tumor cell line does not express glial fibrillary acidic protein, S-100, synaptophysin and neuron-specific enolase.

***Claim Rejections - 35 USC § 112***

The rejection of claims 1-3, 6, 7, 9, 10, 15-18, 20-22, 25, 26, 28, 29, 31-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendments, arguments and cancellation of claims.

The rejection of claims 1-11, 15-33 and 37-40 under 35 U.S.C. 112, first paragraph, because of failure of the specification to enable the full scope of the claims is withdrawn in view of applicant's amendments, arguments and cancellation of claims.

Claim 19 is newly rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable the Artisan to make and/or use the invention. The invention appears to employ novel biological materials, i.e., ATCC Patent Deposit Designation No. PTA-3661. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or otherwise available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the materials (ATCC Patent Deposit Designation No. PTA-3661 in the Claim 19), but there is no indication as to public availability. If the deposit is made under the Budapest treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon issuance of a patent would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide

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assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to MPEP §2400 in general, and specifically to §2411.05, as well as to 37 CFR § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-11, 15-33 and 37-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendments, arguments and cancellation of claims.

Claims 6 and 41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 are indefinite because they do not specifically indicate where the DNA fragment comprising nucleotides 5171-2533 of the SV40 immediate early gene is derived from. Therefore, the metes and bounds of claims 1 and 20 cannot be determined. It would be appropriate to amend the claims to indicate that the DNA fragment comprising nucleotides 5171-2533 of the SV40 immediate early gene is depicted in SEQ ID NO: #.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application

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status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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